IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

RANDALL GOLDMAN *Plaintiff*, vs. ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 4:20-cv-00463

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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Plaintiff Randall Goldman respectfully submits this memorandum brief in support of his motion for summary judgment.[1] Mr. Goldman is entitled to summary judgment because the Secretary is barred by collateral estoppel from denying his claims for Medicare coverage, as a matter of law, and that the coverage denial at issue in this case should be reversed.[2]

Mr. Goldman has repeatedly litigated the issue of whether TTFT is a covered Medicare benefit for him (as well as the sub-issues of, *e.g.*, whether TTFT is "medically reasonable and necessary"/"safe and effective"/not "experimental or investigational"). Mr. Goldman has a prior, final decision from an ALJ finding in his favor on these issues. Nevertheless, the Secretary continues to force Mr. Goldman to re-litigate the identical issues during the time he should be spending with family and focusing on his recovery. This must stop.

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Randall Goldman is a 59-year-old husband of 30 years, father of 4, and former chemical plant operator. Tragically, in 2014, he was diagnosed with an extremely lethal form of brain cancer (GBM). With prior forms of treatment, only 5% of GBM patients are still alive 5 years after diagnosis. As part of his treatment, Mr. Goldman was prescribed a device (TTFT) that slows/stops the spread of the cancer using electrical fields. The use of this device has been shown to nearly

[1] Mr. Goldman offers the following explanation for the timing of this Motion. As this Court may be aware, the issue is pending in many other districts and the Seventh Circuit. Mr. Goldman was hoping he would have updates from other proceedings to inform the Court of by now, to assist in the efficient adjudication of this matter. However, to date, given the lack of development in other proceedings, it is apparent that this Motion must be filed to avoid delay.

[2] Mr. Goldman believes that this case could also be decided on the grounds that the Secretary's decision is arbitrary and capricious and not supported by substantial evidence in light of the decision finding coverage for Mr. Goldman. However, a decision on those grounds would only effect Mr. Goldman and the particular claims at issue here. That is, a decision on a ground other than collateral estoppel will not have broader applicability to either Mr. Goldman or the many other people with GBM that are caught in a litigation trap with the Secretary. By contrast, an issued decision on collateral estoppel will benefit Mr. Goldman in his future claims as well as other litigants more broadly.

triple the five-year survival rate and TTFT has become the standard of care. Mr. Goldman's initial claim for Medicare coverage for TTFT was denied as not "medically reasonable and necessary" and not a covered Medicare benefit. Mr. Goldman retained counsel and appealed. Medicare ALJ Scott Tews found that TTFT was "medically reasonable and necessary" for Mr. Goldman, a Medicare covered benefit, and ordered coverage.

Because TTFT is rented on a monthly basis, Mr. Goldman submitted additional claims for coverage for his TTFT device. Contrary to ALJ Tews, ALJs considering Mr. Goldman's claims have asserted that TTFT is not "medically reasonable and necessary" to treat GBM/a Medicare covered benefit. When the Medicare Appeals Council did not rule on Mr. Goldman's appeals of these negative decisions during the time required by Congress, this case followed.

As set forth below, offensive collateral estoppel may be asserted against the government and collateral estoppel may be applied based on agency proceedings when the agency is acting in a judicial capacity. Given the final, favorable decision of ALJ Tews on exactly the same issue, the Secretary is collaterally estopped from denying coverage of Mr. Goldman's subsequent claims. All the elements for collateral estoppel are present and summary judgment should be granted.

II. STATEMENT OF THE ISSUE

The issue is whether, in light of a prior, final decision determining that TTFT is safe and effective, "medically reasonable and necessary", and a Medicare–covered benefit for Mr. Goldman, the Secretary is collaterally estopped from challenging those factual/legal conclusions to deny the subsequent claims submitted by Mr. Goldman that are at issue here.

III. STANDARD OF REVIEW

Pursuant to 42 U.S.C. § 405(g) (as amended by 42 U.S.C. § 1395ff(b)(1)(A)), "the findings of [the Secretary] *as to any fact*, if supported by substantial evidence, shall be conclusive." (emphasis added). Thus, only factual conclusions are subject to the substantial evidence standard.

For all other issues, the decisions are reviewed using any standard applicable under the Administrative Procedure Act (APA). *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-27 (D.C. Cir. 2012) (applying arbitrary and capricious standard).

IV. STATEMENT OF MATERIAL FACTS

ALJ Tews' Decision Granting Coverage

1. On December 19, 2018, ALJ Scott Tews issued a favorable decision in Appeal No. 1-7718819982 concerning Mr. Goldman's claim for TTFT coverage for the months of July, August, and September 2017. Dkt. 29, Amended Certified Administrative Record 25-40 ("CAR").

2. Mr. Goldman was represented by attorney, Debra Parrish. Dkt. 29, Am. CAR29.

3. ALJ Tews found that TTFT was "medically reasonable and necessary" and a Medicare covered benefit for Mr. Goldman. Dkt. 29, Am. CAR39.

4. The Secretary did not appeal the decision, becoming final February 18, 2019.

ALJ McCormick's Decision Denying Coverage

5. On January 23, 2019, ALJ Kevin McCormick issued an unfavorable decision in ALJ Appeal No. 1-7884275431 concerning Mr. Goldman's claim for TTFT coverage for the months of October 2017-January 2018. Dkt. 29, Am. CAR8-18.

6. ALJ McCormick held TTFT is not considered reasonable and necessary under any circumstances. Dkt. 29, Am. CAR17.

7. ALJ McCormick held that Mr. Goldman was not entitled to Medicare coverage for his TTFT claim and denied coverage. Dkt. 29, Am. CAR17.

ALJ Patterson' Decisions Denying Coverage

8. On July 23, 2019, ALJ Ronald Patterson issued an unfavorable decision in ALJ Appeal No. 1-8454636221 concerning Mr. Goldman's claim for TTFT coverage for the months of May, June, and July 2018. Dkts. 9-11, CAR66-81.

9. ALJ Patterson held that TTFT was not medically reasonable and necessary to treat Mr. Goldman's GBM. Dkts. 9-11, CAR78.

10. ALJ Patterson held that TTFT was not a Medicare covered benefit for Mr. Goldman. *Id.*

11. On August 2, 2019, ALJ Patterson issued an unfavorable decision in ALJ Appeal No. 1-8510955262 concerning Mr. Goldman's claim for TTFT coverage for the months of August, September, October 2018. Dkts. 9-11, CAR4544-4560.

12. ALJ Patterson held TTFT was not medically reasonable and necessary to treat Mr. Goldman's GBM. Dkts. 9-11, CAR4556.

13. ALJ Patterson held TTFT was not a Medicare-covered benefit for Mr. Goldman. Dkts. 9-11, CAR4556.

14. On August 20, 2019, ALJ Patterson issued an unfavorable decision in ALJ Appeal No. 1-8665714599 concerning Mr. Goldman's claim for TTFT coverage for the months of November and December 2018 and January and February 2019. Dkts. 9-11, CAR9058-9074.

15. ALJ Patterson held that TTFT was not medically reasonable and necessary to treat Mr. Goldman's GBM. Dkts. 9-11, CAR9070.

16. ALJ Patterson held TTFT was not a Medicare covered benefit for Mr. Goldman. Dkts. 9-11, CAR9070.

V. FACTUAL BACKGROUND

Mr. Goldman sets forth the following factual background information. While Mr. Goldman does not believe the information here is necessary to grant his motion (though the statements are supported by the Record), a discussion of the factual context may assist the Court.

1. GBM/TTFT

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without

treatment, survival is typically 3 months. With earlier forms of treatment before TTFT, the survival rate at two years is ~31%, while at five years, only ~5% of patients are living.

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)[3] in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.[4] More recently, treating GBM using alternating electric fields developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT from the control group.[5]

As reported, TTFT, an FDA-approved treatment, was the first significant advance in treating GBM in more than a decade. TTFT is the standard of care for treating GBM and essentially all major private insurers cover it. TTFT extends GBM patients' lives, in some cases, by years. It has a Level One recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence,

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[3] The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journals in the world.

[4] *See Stupp, et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); *Stupp, et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

[5] During a clinical study, interim results are measured. When the interim results indicate that the treatment has a significant effect on health or safety, negative or positive, ethical guidelines dictate that the study be halted. Thus, if the interim results indicate that the treatment was significantly more likely to result in death, the study would be halted and the treatment no longer given to the test group. Likewise, if the interim result indicated that the tested treatment was life-saving, the study would be halted and the treatment would be made available to the control group. In those circumstances, withholding the treatment from the control group would be unethical.

that TTFT is a recommended intervention.

The sole supplier of the TTFT device is the manufacturer Novocure, Inc. The Optune system is rented on a monthly basis, leading to monthly claims for Medicare coverage. Sadly, there is no cure for GBM. Patients prescribed TTFT will continue treatment for life as a result.

2. The Medicare Appeals Process

People suffering from GBM and treated with TTFT will have multiple claims for Medicare coverage. Typically, these claims will be submitted every one to three months to reflect their continued usage of the TTFT device. Each claim concerns only the months at issue for that claim.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can, and typically does, take more than a year. At issue in each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928.[6] If the claim is denied, the beneficiary can request "redetermination." *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request "reconsideration." *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary is required to provide "hearings" for appeals to the "same extent" as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the "hearing" by administrative law judges (ALJs). *See* 42 C.F.R. §§ 405.1000-1058. In the case where the beneficiary is represented by counsel, the hearings are adversarial. In such a case, the Secretary's

[6] At issue in this case are claims submitted under "Original Medicare" (*i.e.*, "Medicare Part B"). Accordingly, the regulatory citations herein are those applicable to Part B claims.

representative (Centers for Medicare and Medicaid Services (CMS) or a "contractor" to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary can submit evidence (42 C.F.R. § 405.1018), object to the issues (42 C.F.R. § 405.1024); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. § 405.1037). An ALJ's decision includes findings of fact, conclusions of law, and is based on evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the decision of the ALJ, the Secretary can appeal to the Medicare Appeals Council ("Council"). *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. § 405.1110. In order to be timely, an appeal to the Council (either direct or on own motion review) must be made within 60 days of the ALJ decision date. *See* 42 C.F.R. § 405.1110(a) and (b)(2).

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)). Although the statues and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before they seek relief in a federal court.

3. Local Coverage Determinations

Some discussion of what "LCDs" are may help orient the Court. Much of the Medicare program is not actually run by the Secretary. Instead, the Secretary has divided the country into four regions and hired contractors ("Medicare Administration Contractors") to run the lower levels of the Medicare program. In this capacity, the Contractors themselves develop Local Coverage

Determinations (LCDs) which guide the processing of claims at the initial levels. Thus, Contractors develop LCDs applicable to a device or service for their area. Claims for Medicare coverage (for Part B) are originally submitted to the Contractor for the appropriate region and the Contractor itself applies a relevant LCD to approve or reject a claim. Likewise, when an appeal of an initial denial (a "redetermination") is submitted, that goes to the Contractor - who verifies his earlier decision applying the LCD he developed.

If the claim is denied again and appealed ("reconsideration"), the claim is reviewed by a third party (*i.e.*, the "Qualified Independent Contractor" (QIC)). The QIC is not bound to follow the LCD but if it does not, it must explain its decision. *See* 42 C.F.R. § 405.968(b)(2). Likewise, if the claim is appealed from the QIC, neither ALJs nor the Council are bound by LCDs but, if they do not follow an LCD, they must explain their decision. *See* 42 C.F.R. § 405.1062(a). It is true that LCDs are supposed to consider medical literature, etc. and be reviewed to ensure that they are not outdated. However, unmentioned in the Secretary's paper is that did not happen in the case of TTFT. That is, the LCD that became effective on October 1, 2015 did not consider the suspension of the clinical trial in 2014 on the grounds that withholding TTFT from the control group would have been unethical. Likewise, the LCD was not reviewed after its issuance and did not consider the large number of scientific studies showing the effectiveness of TTFT, additional FDA approval in October 2015, the fact that TTFT had become the standard of care for GBM no later than 2018, as well as clinical trials and seminal papers concerning the same.

Because of this complete failure of process, in May 2019, ALJ Scott Anderson determined that the 2015 LCD concerning TTFT was not supported by substantial evidence. *See* CAR118-122. ALJ Anderson's decision was the result of a challenge by a Medicare beneficiary (*i.e.*, the "Aggrieved Party") contending that the LCD was not supported by substantial evidence.

Thereafter, the Contractor submitted a revised LCD (that is also being challenged) that only applies to dates of service after September 1, 2019. As a result, the original LCD is deemed invalid. *See* 42 C.F.R. §§ 426.420(b); 426.460(b). Accordingly, the LCD that was used to deny coverage of Mr. Goldman's claims by ALJs McCormick and Patterson has been invalidated. This is a separate reason why the decisions at issue denying coverage should be reversed on the merits. Nevertheless, a proper application of collateral estoppel will prevent Mr. Goldman, and this Court, from having to bear the burden of litigating the same issues again and again.

VI. LEGAL BACKGROUND

Collateral estoppel (*i.e.*, "issue preclusion") is a venerable common law doctrine that bars re-litigation of a legal or fact issue decided in a prior proceeding. Under the doctrine, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. United States*, 440 U.S. 147, 153-54 (1979).

Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

In the Fifth Circuit, collateral estoppel applies when: 1) the issue at stake is identical to the one involved in the prior action; 2) the issue was actually litigated in the prior action; and 3) the

determination of the issue in the prior action was part of the judgment in the earlier action. *See, e.g., Southmark Corp. v. Coopers & Lybrand*, 163 F.3d 925, 932 (5th Cir. 1999).[7]

As detailed above, Mr. Goldman has litigated multiple claims before the Secretary in parallel/concurrently. Parallel/concurrent litigation is common. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922). Thus, even a later filed suit that reaches finality first may have preclusive effect in an earlier filed, still on-going, litigation. For example, in *Chicago, R.I. & P. RY, Co., v. Elder*, 270 U.S. 611 (1926), the Supreme Court held:

> Nor is it material that the action proceeding, in which the judgment, set up as an estoppel, is rendered, was brought after the commencement of the action or proceeding in which it is pleaded. … Whenever a judgment is rendered in one of the courts and pleaded in the other the effect of that judgment is to be determined by the application of the principles of res judicata by the court in which the action is still pending in the orderly exercise of its jurisdiction, as it would determine any other question of fact or law arising in the progress of the case.

Id. at 615-16.[8] *See also Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Proctor & Gamble Co. v. Amway Corp.*, 376 F.3d 496, 500 (5th Cir. 2004) ("When two suits proceed simultaneously, as in this case, *res judicata* effect is given to the first judgment rendered."); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) ("The first to reach final decision can affect the other … through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]"). In other words, a later-filed or decided case that reaches finality first may have preclusive effect on

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[7] A slightly different formulation of the same elements was presented in *Wehling v. Columbia Broadcasting System*, 721 F.2d 506, 508 (5th Cir. 1983). The showing made below with respect to *Southmark* is equally applicable to the *Wehling* formulation.

[8] "Res judicata" is a legal doctrine incorporating the concepts of "claim preclusion" (formerly known as "merger" and "bar") and "issue preclusion" (formerly known as "collateral estoppel"). The confusing use of these terms led to modern efforts to limit "res judicata" to mean "claim preclusion" and to use the term "issue preclusion" instead of "collateral estoppel." *See* THE RESTATEMENT (SECOND) OF JUDGMENTS (1982); *Migra v. Warren City School District Board of Education*, 465 U.S. 75, 77 n. 1 (1984).

an earlier-filed, but still on-going litigation.

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). Only a party to a prior proceeding with the government can assert collateral estoppel against the government. Here, Mr. Goldman is not seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than himself. Instead, Mr. Goldman contends that he should not have to relitigate the same coverage issues against the Secretary that have been finally and conclusively determined in his favor.[9]

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted). *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-3 (2015) (confirming that administrative decisions can be a basis for issue preclusion).

[9] Further, Mr. Goldman's claim of collateral estoppel is limited to the decisions at issue. Whether the Secretary will be estopped on future claims by Mr. Goldman will depend on whether Mr. Goldman submits them and whether there are "changed circumstances."

As set forth in *Astoria*, there is a presumption that common law principles (including collateral estoppel) apply to administrative decisions where an agency is acting in a "judicial capacity." *Astoria*, 501 U.S at 108 ("where a common-law principle is well established, as are the rules of preclusion, the court may take it is as a given that Congress has legislated with an expectation that the principle will apply except where a statutory purpose to the contrary is evident."). A party asserting that collateral estoppel does not apply bears the burden of establishing the presumption has been overcome. *See Green v. Block Laundry Machine Co.*, 490 U.S. 504, 521 (1989) ("has the burden of showing that the legislature intended such a change.").

To overcome the presumption of the common law, the party so asserting must demonstrate that Congress evidenced an intent to do so. *Astoria*, 501 U.S. at 109-110 (common law applies "absent clearly expressed congressional intent to the contrary"); *U.S. v. Texas*, 507 U.S. 529, 535 (1993) ("an expression of legislative intent to supplant"); *Green*, 490 U.S. at 521 (must show "legislature intended such a change").

Moreover, to overcome the presumption, a statute must "speak directly" to the common law issue. *See Texas*, 507 U.S. at 534 ("In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law.") (internal citations/quotations omitted). Statutes which are compatible with the pre-existing practice of the common law do not overcome the presumption. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994).

The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed. App'x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ' work determination); *Drummond v. Comm'r of Social Security*, 126 F.3d 837, 841-43 (6th Cir. 1997) (SSA collaterally estopped by prior ALJ work determination); *Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir.

1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. United States*, 570 F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *C & N*, 953 F. Supp. 2d at 912-14 (defendant collaterally estopped by prior TTAB proceeding); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination). *See also DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992, 1001 (D. Neb. 2002) ("The Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit.").

VII. ARGUMENT

As a result of the final decision finding TTFT to be a covered benefit/"medically reasonable and necessary" for Mr. Goldman, the Secretary is collaterally estopped from issuing denials on the same grounds that were rejected by the other final decision. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court should reverse the Secretary's denial, order coverage, and remand this case with instructions to the Secretary to effectuate the Court's decision.

The Secretary cannot carry his burden of rebutting the presumption that collateral estoppel applies to Medicare cases. No portion of the Medicare statute "speaks directly" to the issue of collateral estoppel or clearly expresses Congress' intent to abrogate the common law. Further, all portions of the statute are compatible with the pre-existing practice of collateral estoppel. As to the application of collateral estoppel in this particular case, Mr. Goldman tracks the elements laid out in *Southmark*. *Southmark*, 163 F.3d at 932.

1. The Department Was Acting in a "Judicial Capacity"

Out of an abundance of caution, Mr. Goldman addresses the issue of whether the Department was acting in a "judicial capacity" when it issued the prior decision and whether the procedures adopted by the Secretary provided the Secretary with a fair opportunity to present his case. There no dispute on either point.

As an initial matter, pursuant to the statute, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence in conducting the hearings. *See* 42 U.S.C. § 405(b). The Secretary has further issued regulations confirming the "judicial" and adversarial nature of the hearings and providing the Secretary a fair opportunity to present his case.

As detailed above, at a minimum when the beneficiary is represented, "hearings" before the Secretary are conducted by ALJs and the Secretary (through his representatives) has an opportunity to submit evidence, object to the timing of the hearing, object to the issues at the hearing, present evidence in the form of documents/witnesses (including through subpoenas), take discovery, cross-examine witnesses, and present argument. *See* 42 C.F.R. §§ 405.1018, 1020, 1024, 1026, 1036, and 1037. The ALJ issues a written decision including findings of fact and conclusions of law. *See* 42 C.F.R. § 405.1046. Further, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Council using the procedures of 42 C.F.R. §§ 405.1100-1140 (appeal as a party) or 42 C.F.R. § 405.1110 ("own motion review").

Pursuant to the Secretary's own regulations, where (as here) the beneficiary was represented by counsel, the Secretary had the full panoply of rights as a litigant (conducting discovery, presenting evidence, cross-examination, etc.) including the right to appeal. ALJ Tews issued a written decision setting forth the bases for his decision. Thus, the Secretary was acting in a "judicial capacity" when ALJ Tews issued the decision giving rise to collateral estoppel here.

2. The Issue at Stake in the Appealed Decisions is Identical to the One Involved in the Prior Action

At issue in any Medicare coverage litigation is whether the device/service is a Medicare covered benefit for the beneficiary. This conclusion involves the sub-issues of whether the device/service is "medically reasonable and necessary" for the beneficiary and the further sub-

issue of whether the device/service is "safe and effective."[10] *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (any item which is not "medically reasonable and necessary" is excluded from coverage). Thus, when a coverage decision indicates that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that beneficiary as well as that the device/service is "safe and effective." As noted above, these are the issues ALJ Tews decided. *See* Amended CAR39.

Likewise, the identical issues were at stake and decided by ALJs McCormick and Patterson when they reached the opposite conclusions, which the Secretary is collaterally estopped from contesting. *See* Amended CAR17; CAR78, 4556, 9070. Thus, the issues at stake in ALJ McCormick and Patterson's decisions are identical to the ones involved in ALJ Tews' decision.

To the extent the Secretary contends that the issues are different because each decision cover particular months of treatment, there is no merit to that claim. It is well settled that the test for determining whether facts/issues are the same between two decisions for collateral estoppel purposes is "materiality." That is, facts/issues are the same unless they are materially different with respect to the conclusions reached (*i.e.*, "changed circumstances"). *See, e.g., Montana v. U.S.*, 440 U.S. 147, 159 (1979) ("changes in facts essential to a judgment will render collateral estoppel inapplicable"); *Bernstein v. Bankert*, 733 F.3d 190, 226 (7th Cir. 2013) ("identical in all material aspects"); *Scooper Dooper, Inc., v. Kraftco Corp.*, 494 F.2d 840, 846 (3rd Cir. 1974). Here, there is no evidence that there is a material difference as to whether TTFT was safe and effective and "medically reasonable and necessary" in, *e.g.*, September 2017 (when ALJ Tews held it was) and October 2017 (when ALJ McCormick held it was not). The issues are identical.

[10] Under Medicare's rules, it can never be "medically reasonable and necessary" to provide a device/service that is not "safe and effective."

3. The Issue Was Actually Litigated in the Prior Action

As detailed above, the issue of whether Medicare coverage exists for Mr. Goldman's TTFT was actually litigated in the proceedings before ALJs Tews, Patterson, and McCormick (as well as the sub-issues of whether the device/service is "medically reasonable and necessary" for the beneficiary and the further sub-issue of whether the device/service is "safe and effective.").

Moreover, unlike a default, Mr. Goldman was put to his burden of proof before ALJ Tews. *See, e.g.,* CAR33 ("[t]he burden of proving each element of a Medicare claim lies with the Appellant by preponderance of the evidence.") (sic). *See Restatement (Second) of Judgments* § 27 cmt. d (1982) ("When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination and is determined, the issue is actually litigated."); *Matter of Garner*, 56 F.3d 677, 680 (5th Cir. 1996) (defendant who answered Complaint but did not otherwise appear bound by collateral estoppel as plaintiff was put to burden of proof). The issue of whether TTFT is a Medicare-covered benefit (and the relevant sub-issues) by ALJs Patterson and McCormick and the Council was actually litigated in the prior action before ALJ Tews.

4. The Determination of the Issue Was Part of the Judgment In the Prior Action

Of course, the base issue in each Medicare coverage dispute is whether an item/service is a Medicare covered benefit. Thus, the determination on that issue was necessary to the outcome of the proceedings before ALJ Tews (on which collateral estoppel is based) just as it was for the decisions of ALJ Patterson, ALJ McCormick, and the Council. Likewise, because there could be no determination that TTFT was a Medicare covered benefit for Mr. Goldman without a determination that TTFT was "medically reasonable and necessary" for him, that determination was part of the final judgments. Likewise, because whether something is "medically reasonable and necessary" is itself dependent on whether it is "safe and effective", again, that finding was

part of the final judgments. Thus, determination of the same issues on which preclusion is sought was part of the judgments by ALJ Tews.

In other cases, the Secretary has asserted that unappealed decisions of ALJs are not "final." There is nothing to this claim. The favorable decision of ALJ Tews is a final decision by an ALJ within the jurisdiction of the Secretary's Department itself. *See, e.g.*, CAR13 ("ALJs within OMHA issue final decisions of the Secretary except for decisions reviewed by the Medicare Appeals Council."); 70 Fed.Reg. 36386-7 (June 23, 2005) ("The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]"); 42 C.F.R. § 405.1102 ("… a written request for a Council review within 60 calendar days …").

Separate from the Secretary's statements, the decision of ALJs Tews is also final pursuant to the guidance of the Supreme Court. *See Smith v. Berryhill*, 139 S.Ct. 1765, 1775-76 (2019) (under APA, action is "final" if it: 1) marks the consummation of the agency's decision-making process; and 2) is one by which rights have been determined or from which legal consequences will flow). As Secretary failed to appeal ALJ Tews' decision, it marked the consummation of the decision-making process and by which Mr. Goldman's rights were determined.

5. The Secretary Had a Fair Opportunity to Litigate the Issue in the Prior Proceedings & Applying Collateral Estoppel Would Be Fair To Both Parties

While it does not appear that opportunity to litigate or "fairness" are elements of collateral estoppel in this Circuit, Mr. Goldman addresses them to avoid counterarguments. As indicated, Mr. Goldman was represented in the case before ALJ Tews. Thus, pursuant to 42 C.F.R. §§ 405.1008 and 405.1010, the Secretary had the full rights of a litigant. In other cases, the Secretary alleged that the volume of ALJ appeals made the application of collateral estoppel "unfair" and/or

that the Secretary did not have a fair opportunity to litigate. For example, in *Oxenberg v. Azar*, Case No. 20-cv-738 (E.D. Pa.), the Secretary alleged:

> "It is impracticable for the Secretary to appear as a party in the *over 400,000* Medicare claim appeals that are filed each year at the ALJ level." *See* Dkt. #17 at 2-3 (emphasis in original);
>
> "Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate hundreds of thousands of appeals annually." *See* Dkt. #17 at 27.

The Secretary made these same or similar representations in *Christenson v. Azar,* Case No. 20-cv-194 (E.D. Wisc.); *Townsend v. Azar*, Case No. 20-cv-1210 (S.D.N.Y.); and *Piekanski v. Azar*, Case No. 20-cv-687 (M.D. Pa.). Mr. Goldman believes that this is all irrelevant because the Supreme Court affirmed the application of collateral estoppel against the government knowing the government was (at that time) a party to ~33% of all litigation in the U.S. *See U.S. v. Mendoza*, 464 U.S. 154, 159-60 (1984). Thus, whatever the number of appeals, the Secretary is still subject to collateral estoppel. Further, as Mr. Goldman pointed out, under the Secretary's own regulations, the total number of appeals is irrelevant because the Secretary may only appear as a party in appeals where the beneficiary is represented. Thus, appeals where the Secretary could not appear add no burden on the Secretary.

In similarly situated cases, the plaintiffs sought discovery on the number of appeals where the beneficiary was represented. The Secretary resisted providing that information, ultimately requiring motion practice in two courts and two hearings. When the Secretary was ordered to provide the information, the reason for the Secretary's intransigence became clear.

On October 27, 2020, the Secretary served interrogatory answers indicating that in FY2019, the number of ALJ appeals filed where the beneficiary was represented (and the Secretary, therefore, was permitted to participate) was 2,602 - nationwide. *See* **Exhibit "A"**. Thus, rather than appearing as a party in over 400,000 Medicare claim appeals that are filed each

year at the ALJ level, or the Secretary appearing as a party in the ~44,000 ALJ appeals filed each year, or the Secretary appearing as a party in the ~5,100 beneficiary appeals filed each year, the Secretary could have actually appeared in a maximum of 2,602 represented beneficiary appeals filed at the ALJ level in FY2019. That is only 0.65% of the 400,000 appeals the Secretary represented to other courts, or about 50 represented beneficiary appeals filed each week.

Further, the Secretary has published data indicating that in FY2019 more than 54% of the appeals filed were dismissed (*e.g.*, as untimely).[11] Multiplying this rate by the number of represented beneficiary appeals and subtracting that from the total, results in 1,415 represented beneficiary appeals. In only 1,415 cases a hearing was presumably held (or the decision issued on the record) and a decision issued. On average that is 27 ALJ hearings per week.[12]

To be clear, these are the maximum number of ALJ hearings the Secretary could appear in, if he so chose. Alternatively, the Secretary could rely on the fact that the beneficiary bears the burden of proof and choose not to attend (as he did here). Even in the cases where the Secretary chooses not to appear, the Secretary can appeal a negative decision on "own motion review." The Secretary had a full and fair opportunity to litigate.

6. Applying Collateral Estoppel is Consistent with the Purpose of the Doctrine

Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results.

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[11] *See* https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html (last visited October 28, 2020).

[12] *See* the attached Declaration of Debra M. Parrish regarding the volume of ALJ appeals a small law firm can handle, attached as **Exhibit "B"**.

Allen, 449 U.S. at 94; *Parklane*, 439 U.S. at 326. In the present case, there is no explanation for the inconsistent result of life-extending treatment being medically reasonable and necessary one month and then not the next month. Applying collateral estoppel prevents this inconsistency.

Likewise, applying collateral estoppel would be consistent with the other purposes of collateral estoppel in terms of avoiding the needless burden and expense on the parties and the courts. Given that Mr. Goldman will have claims for TTFT coverage for the remainder of his life (typically submitted every three months to Medicare), absent the application of collateral estoppel, Mr. Goldman himself could result in as many as four cases/year on this Court's docket.

VIII. CONCLUSION

The Secretary should be collaterally estopped from denying that TTFT is a covered Medicare benefit and "medically reasonable and necessary" for Mr. Goldman. Mr. Goldman has sustained his burden of proving coverage and should not be tormented by repeated litigation. The denials of Mr. Goldman's claims that were the subject of ALJ McCormick and Patterson's decisions should be reversed.

For the reasons above, pursuant to 42 U.S.C. § 405(g) (fourth sentence), Mr. Goldman respectfully requests that this Court grant this Motion for Summary Judgment and remand this case to the Secretary with instruction to provide coverage of the rejected claims.

Respectfully submitted this December 30, 2020.

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I certify that the above document was served via email on the Court's CM/ECF system to all counsel of record on December 30, 2020.

s/ *Austin K. Yancy*
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